DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 30, 2015

Curative Medical Inc.
Bill Jacqmein
Regulatory Affairs Consultant
1591 Deephaven Dr.
Woodbury, Minnesota 55129

Re: K141354
Trade/Device Name: Navajo PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: PTA Balloon Dilatation Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: May 15, 2014
Received: December 24, 2014

Dear Bill Jacqmein,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Navajo PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*

The NavajoTM PTA balloon dilatation catheter is intended to dilate stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries); and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Submitter:	Curative Medical Inc. 3227 Kifer Road Santa Clara, CA 95051 Establishment Number: 3008361782
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Email:	bjacqmein@gmail.com
Date Prepared:	15 May 2014
Proprietary Name:	Navajo PTA Balloon Dilatation Catheter
Common Name:	Percutaneous catheter
Product Code:	LIT –Catheter, Angioplasty, Peripheral, Transluminal
Device Classification:	Class II, 21 CFR 870.1250 – Percutaneous Catheter
Predicate Devices:	AgilTrac .035 Peripheral Dilatation Catheter (K022738)

Device Description:

The Navajo™ PTA Balloon Dilatation Catheter is an over-the-wire Percutaneous Transluminal Angioplasty (PTA) catheter consisting of a proximal adaptor, coaxial lumen shaft, and a distal dilatation balloon. The Navajo PTA Balloon Dilatation Catheter is compatible with guide wires with a maximum diameter of 0.035" and with 5F to 7F introducer sheaths, depending on the diameter and balloon length of the dilatation balloon. The catheter is provided with a hydrophilic coating on the shaft and is available in useable catheter lengths of 80, 100, 120 and 130cm.

Intended Use:

The Navajo™ PTA balloon dilatation catheter is intended to dilate stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries); and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Comparison of Technological Characteristics:

The Navajo™ PTA balloon dilatation catheter incorporates substantially equivalent device materials, configurations, packaging, technology, sterilization process and intended use as those featured in the AgilTrac .035 Peripheral Dilatation Catheter.

Characteristic	Proposed compared to Predicate
Components	Same components, similar configuration, design and function.
Materials	Same materials
Packaging	Same Packaging
Guidewire compatibility	Same compatibility
Balloon Lengths	Similar Lengths; Navajo™ Lengths are inside the minimum and maximum range of the predicate device.
Effective Length	Similar Lengths; Navajo™ Lengths are inside the minimum and maximum range of the predicate device
Rated Burst Pressure (RBP)	Same or higher RBP; better safety margin for Navajo™
Intended Use	Same intended use

Summary of Performance Data and Substantial Equivalence:

Navajo™ PTA Balloon Dilatation Catheters were designed and verified in accordance with the risk analysis and product requirements. All tests confirmed the products met the pre-defined acceptance criteria. Curative Medical Inc. has determined that the Navajo™ PTA Balloon Dilatation Catheters are safe and effective. The Navajo™ PTA Balloon Dilatation Catheters have been tested and shown to be compliant with the following standards documents:

- ISO 10555-1:2009- Sterile, single-use intravascular catheters – Part 1: General requirements
- ISO 10555-4:1996- Sterile, single-use intravascular catheters – Part 4: Balloon dilatation catheter
- ISO 10993-1:2009- Biological evaluation of medical devices – Part 1: Evaluation and testing

- ISO 10993-4:2002+AMD1:2006-Biological testing of medical and dental materials and devices – Part 4: Selection of tests for interactions with blood
- ISO 10993-5: 2009- Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2006- Biological testing of medical and dental materials and devices – Part 11: Tests for systemic toxicity
- EN ISO 11135-1: 2007 Sterilization of Medical Devices – Validation and routine control of ethylene oxide sterilization
- EN ISO 11607-1: 2009- Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

Performance Testing:

The following performance tests were completed:

Catheter Dimension, Balloon & Tip Profile
Catheter Prep, In/deflation Time
Catheter Fatigue Integrity
Balloon Compliance
Balloon Rated Rupture Pressure
Catheter Shaft Pressure Integrity
Catheter Interface Compatibility, GW Lumen Collapse Pressure
Catheter Luer – Shaft Tensile Strength
Catheter Shaft – Balloon Bond Tensile Strength
Catheter Soft Tip Tensile Strength
Catheter Shaft Coating Integrity
Catheter Flexibility, Kink and Torque Strength

This 510(k) submission presents the results of the testing and detailed descriptions to demonstrate that Navajo PTA Balloon Dilatation Catheter is substantially equivalent to the AgilTrac .035 Peripheral Dilatation Catheter (K022738).

Conclusion:

Based on the indications for use, technological characteristics, safety and performance testing, the Navajo™ PTA Balloon Dilatation Catheter has been shown to be appropriate for its intended use and is considered substantially equivalent to the AgilTrac .035 Peripheral Dilatation Catheter (K022738).